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| 10/065,846 | 11/25/2002 | Richard Philip Mallozzi | 130733 | 9713 |
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| GENERAL ELECTRIC COMPANY GLOBAL RESEARCH PATENT DOCKET RM. BLDG. K1-4A59 NISKAYUNA, NY 12309 | | | RAMIREZ, JOHN FERNANDO | |
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| | | | 3737 | |

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TWA

Office Action Summary**Application No.**

10/065,846

Applicant(s)

MALLOZZI ET AL.

Examiner

John F. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/23/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed on November 23, 2005 have been fully considered but they are not persuasive. In relation to claims 1 and 16, applicant alleges that Wischmann does not disclose the step of acquiring phantom images at different times or imaging sessions and thereafter using the variations to correct examination images.

However, the examiner of record respectfully disagrees with applicant's comments. In column 2, lines 20-40, the specification of the Wischmann patent specifically states:

20 Because the phantom body is arranged in the imaging
zone during the formation of the images, distortions then
occurring can be immediately detected and corrected. Image
points of the phantom body appear in each image. In this
context image points are to be understood to mean points at
25 which points of the phantom body are imaged in the images.
From a number of such image points in different images, for
example a so-called phantom image can be readily
constructed, that is to say an image of the phantom body.
This phantom image is compared with the real phantom
body whose structure and coordinates in space are known;
30 this comparison reveals which distortions have occurred
during the formation of the images and also reveals the effect
of these distortions. From this comparison there can also be
derived a correction rule which describes the distortions
occurring and on the basis of which the images formed can
35 be corrected. This ultimately results in a substantially
enhanced accuracy of the images, so that positions in the
image at which, for example a tumor is situated can also be
very accurately converted into positions within the patient.

Based on the above evidence, the system disclosed by Wischmann teaches the step of acquiring phantom images at different times or imaging sessions and thereafter using the variations to correct examination images. Specifically, the specification clearly

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discloses the step of comparing phantom images to derive a correction rule, which describes the distortions, and finally using the variations to correct the images.

In relation to claim 16, it is noted for the record that a recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claims. In re Pearson, 494 F. 2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F. 2d 576, 152 USPQ 235 (CCPA 1967). Accordingly, since claim 16 is an apparatus claim, and not a method claim, the intended uses disclosed by the applicant do not provide the necessary patentable weight to overcome the pending rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 11, 16, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wischmann et al. (US 5,872,829).

In regards to claims 1 and 11, Wischmann et al. discloses a method for correcting at least one of examination images and measurements acquired by a magnetic resonance imaging (MRI) device by imaging a phantom of known structure at selected intervals to generate phantom images (see Abstract, and col. 4, lines 45-48), performing automatic analysis of the phantom images relative to images of the phantom acquired at a previous time (col. 2, lines 20-22), calculating variations between respective phantom images, and correcting the at least one of examination images and measurements using the calculated variations between phantom images (col. 2, lines 25-36).

In reference to claim 2, Wischmann et al. discloses the correcting step is automatically initiated within an image processor of the MRI device (col. 1, lines 10-15; col. 2, lines 19-21).

In reference to claims 16, 17 and 20, Wischmann et al. discloses a system for performing Magnetic Resonance Imaging (MRI) examinations (col. 4, lines 45-48), an imaging device for acquiring images of regions of interest within a subject and a phantom of known structure (col. 6, lines 57-59; see Abstract), an image processor adapted to analyze images of the phantom and calculate scanner related variations and further adapted to automatically correct at least one of images of regions of interest and measurements of the regions of interest within the subject based on the calculated variations (col. 2, lines 19-36 ; col. 1 lines 10-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 6, 7 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wischmann.

In regards to claims 3, 6, 7 and 12, It is inherent that a phantom includes an outer structure and substructures representing different body parts and hence necessary these structures must emit different signal strengths to determine respective locations of the substructures within the respective phantom images providing information to calculate and correct changes in the locations of the substructures. In the alternative, it would have been obvious to one skilled in the art to use a phantom having multiple substructures that closely represents the human body if the correction of image of choice are those of a human body having multiple substructures and hence different signal strengths would be detected from the various substructures.

Claims 4, 5, 8-10, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wischmann et al., in view of DeCarli et al. (US 5,262,945).

In reference to claims 4, 8, 9, and 10, Wischmann et al., teaches all the limitations of the claimed subject matter except for mentioning specifically the step of acquiring images at a first imaging session and at least one successive imaging session for tracking progression of a given disease, generating corrected examination images

and volume measurements are generated based on the corrected examination images, correcting volume measurements using a scaling correction map for adjusting the volume measurements, and additionally, performing longitudinal examinations of a set of anatomical structures and repeating the imaging, performing and measuring steps for at least one successive examination for tracking the measured regions of interest .

Concerning claims 5, 18 and 19, Wischmann et al., does not disclose the disease is a neurodegenerative disease and the examination images are used to generate volume measurements of a brain, and the images of the regions of interest are acquired at a first imaging session and at least one successive imaging session for tracking progression of a given disease.

However, the steps of (1) acquiring images at a first imaging session and at least one successive imaging session for tracking progression of a given disease, (2) generating corrected examination images and volume measurements are generated based on the corrected examination images, (3) correcting volume measurements using a scaling correction map for adjusting the volume measurements, (4) performing longitudinal examinations of a set of anatomical structures and repeating the imaging, (5) performing and measuring steps for at least one successive examination for tracking the measured regions of interest, (6) the disease is a neurodegenerative disease and the examination images are used to generate volume measurements of a brain, and (7) the images of the regions of interest are acquired at a first imaging session and at least one successive imaging session for tracking progression of a given disease are

considered conventional in the art as evidenced by the teachings of DeCarli et al. (US 5,262,945).

The DeCarli et al. patent teaches the steps of acquiring images at a first imaging session and at least one successive imaging session for tracking progression of a given disease, generating corrected examination images and volume measurements are generated based on the corrected examination images, correcting volume measurements using a scaling correction map for adjusting the volume measurements, performing longitudinal examinations of a set of anatomical structures and repeating the imaging, performing and measuring steps for at least one successive examination for tracking the measured regions of interest, the disease is a neurodegenerative disease and the examination images are used to generate volume measurements of a brain, and the images of the regions of interest are acquired at a first imaging session and at least one successive imaging session for tracking progression of a given disease.

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Wischmann et al., with the above discussed enhancements would have been considered obvious because such modifications would have provided a method to analyze, correct, classify and monitor regional volumes in brain structures as they change with healthy aging and brain disease using special magnetic resonance imaging sequences.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wischmann et al., in view of Kennedy et al. (US 5,185,809). Wischmann et al. does not disclose the step in which the regions of interest are substructures within the brain.

However, the step in which the regions of interest are substructures within the brain is considered conventional in the art as evidenced by the teachings of Kennedy et al. (US 5,185,809).

The Kennedy et al. patent teaches the step in which the regions of interest are substructures within the brain.

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Wischmann et al., with the above discussed enhancements would have been considered obvious because such modifications would improve MRI interpretations: sequential volumetric analyses of any structure, inflammatory or degenerative processes within the brain would provide sufficient sensitivity to identify subtle but significant changes in volume, providing more precise identification and quantification of subtle neurologic disease progression.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wischmann et al., in view of Jack et al. (US 2003/0135105). Wischmann et al. does not disclose the step to register successive images of the anatomical structures.

However, the step to register successive images of the anatomical structures is considered conventional in the art as evidenced by the teachings of Jack et al. (US 2003/0135105).

The Jack et al. patent teaches the step to register successive images of the anatomical structures.

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Wischmann et al., with the above discussed

enhancements would have been considered obvious because such modifications would help compared and interpreted the magnetic resonance images acquired at different times by aligning the images during a series of examinations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John F. Ramirez whose telephone number is (571) 272-8685. The examiner can normally be reached on (Mon-Fri) 7:30 - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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